

Testing the effectiveness of a web-based intervention to reduce alcohol consumption

Submission date 07/09/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/12/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Misuse of alcohol and alcohol dependence are a growing problem worldwide. Many people show signs of drinking too much alcohol, or drinking alcohol at inappropriate times (hazardous alcohol use), and are at risk of developing alcohol dependence, often known as "alcoholism". It is thought that the best way of preventing alcohol dependence is to better educate people who are at risk of developing it. Providing an inexpensive self-help programme using the internet to prevent people from developing full alcohol-dependence could be very beneficial from a public health point of view. The aim of this study is find out whether the use of a web-based self-help programme for hazardous alcohol users can help to reduce alcohol intake.

Who can participate?

Adults who are hazardous alcohol users but not clinically depressed.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in the first group (intervention group) are started on a 6 week self-help programme focusing on alcohol use via the internet. This programme provides education materials as well as teaching self-control practices and techniques to reduce cravings. The participants are asked to keep a diary throughout the 6 week intervention, in order to study their thoughts on the programme and see how well the treatment is working. Those in the second group (control group) are put on a waiting list. After 6 months on the waiting list, those in the control group are given the opportunity to start the online self-help programme. For both groups, at the start of the study, at three months and at six months, alcohol consumption is measured, as well as mental health issues (such as depression). The cost-effectiveness of the programme is also measured at these time points.

What are the possible benefits and risks of participating?

Benefits of participating include a better understanding of addictive behaviour and being given tools to help handle cravings and reducing the risk of alcohol dependency. Potential risks of participating are insignificant, however withdrawal symptoms, such as cravings, may be experienced.

Where is the study run from?

1. Swiss Research Institute for Public Health and Addiction (Switzerland)
2. Leuphana University (Germany)
3. Arkin Mental Health Care (Netherlands)
4. Amsterdam Institute for Addiction Research (Netherlands)
5. VU University of Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?

November 2015 to January 2018

Who is funding the study?

Swiss Foundation for Alcohol Research (Switzerland)

Who is the main contact?

Dr Michael Schaub

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Web-based Treatment Trial among Problematic Alcohol Users

Study objectives

Tailored self-help for the reduction of alcohol use is more effective than the waiting list control condition in reducing alcohol use between the baseline and the 3 and 6 months follow-ups.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Canton of Zurich, 01/09/2015, ref: KEK-ZH-Nr: 2015-0082

Study design

Randomised controlled trial with web-based psychological intervention

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet**Health condition(s) or problem(s) studied**

Harmful or hazardous alcohol use

Interventions

After ensuring that potential participants are eligible for the study (i.e., after a baseline assessment), they will be randomized by a computer program to 1 of 2 parallel groups:

1. Experimental intervention: web-based self-help program focusing on alcohol; and
2. Control condition: waiting list.

The web-based self-help intervention (study arm 1) consist of a diary (assesses daily alcohol consumption) and several (currently 8) modules based on the principles of motivational interviewing, self-control practices, and methods of cognitive behavioural therapy. Participants can study all modules at their own pace and in their own order, though a specific order will be advised. This web-based self-help intervention consist of a 6-week program starting individually at the point of the user's online registration. Follow-ups will be assessed 3 and 6 month after the individual's self-chosen starting point. The control condition is a waiting-list. The follow-ups are timed as in the experimental intervention (after 3 and 6 months). After 6 months the study phase of the control condition is finished and people will be given the opportunity to start the self-help programme of the experimental condition.

Intervention Type

Behavioural

Primary outcome measure

The number of weekly standard drinks will be assessed with timeline follow-back (TLFB) at baseline, 3 months and 6 months.

Secondary outcome measures

1. Depressive symptoms assessed with the "Center of Epidemiologic Studies of Depression" (CES-D-20) at baseline, 3 months and 6 months
2. Use of tobacco and illicit drugs assessed with the "Fragebogen Substanzanamnese" questionnaire (FDA) at baseline, 3 months and 6 months
3. Changes in mental health symptoms assessed with the Mental Health Inventory questionnaire (MHI-5) at baseline, 3 months and 6 months
4. Treatment retention measured by using the diary every week over the 6-weeks of intervention
5. Cost-effectiveness-analyses assessed with the EuroQol Quality of Life questionnaire (EQ-5D-3L) at baseline, 3 months and 6 months
6. Cost-utility-analysis and client intervention satisfaction assessed with the Questionnaire on healthcare utilization and productivity losses (TiC-P) at baseline, 3 months and 6 months
7. The "Customer Satisfaction Questionnaire" (CSQ-8) is used as secondary outcome only for participants who have received web-based self-help intervention for 6 weeks (i.e., not used for the control group) measured every week over the 6-weeks of intervention
8. Drinking behaviour is determined using the total score of the short version of the Alcohol Use Disorders Identification Test (AUDIT-C) at baseline, 3 months and 6 months

Overall study start date

01/11/2015

Completion date

31/01/2018

Eligibility**Key inclusion criteria**

1. Aged 18 years or over
2. AUDIT score ≥ 8 and ≤ 20 (AUDIT = Alcohol Use Disorder Inventory Test)
3. CES-D-20 score < 16 (Center of Epidemiological Studies of Depression)
4. Weekly Internet access

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

520 (2 groups of 260)

Key exclusion criteria

1. Participation in other psycho-social or pharmacological treatments for the reduction /cessation of alcohol use or the reduction of depression symptoms
2. Use of opioids or stimulants in the last 12 months and/or cannabis use of more than once a week in the previous 30 days
3. Previous treatment for cardiovascular problems
4. Suicidal thoughts or plans in the last 12 months
5. Pregnancy or breast feeding in female participants

Date of first enrolment

01/11/2015

Date of final enrolment

31/07/2017

Locations**Countries of recruitment**

Germany

Netherlands

Switzerland

Study participating centre

Swiss Research Institute for Public Health and Addiction

Konradstrasse 32

Zurich

Switzerland

8031

Study participating centre

Leuphana University

Scharnhorststraße 1

Lüneburg

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Study participating centre

Arkin Mental Health Care

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Netherlands

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Study participating centre
Amsterdam Institute for Addiction Research
Meibergdreef 5
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Sponsor information

Organisation
Swiss Foundation for Alcohol Research

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Sponsor type
Government

Funder(s)

Funder type
Research organisation

Funder Name
Swiss Foundation for Alcohol Research

Results and Publications

Publication and dissemination plan

Not provided at time of registration.

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request